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Sangeeta N. Bhatia

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MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER

TENTONI, LEO B

ART UNIT

PAPER NUMBER

1791

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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DETAILED ACTION

Election/Restrictions

1. Claims 39-44 and 54-59 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 20 April 2007.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 has been amended to depend from claim 40, which has been withdrawn from further consideration due to a requirement for restriction. Therefore, claim 64 does not further limit the subject matter of any preceding claim currently under consideration.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the

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differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 30, 34, 38, 45, 46, 48, 49, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al (U.S. Patent 6,143,293 A) in combination with Kale et al (U.S. Patent Application Publication 2002/0127711 A1).

Weiss et al (see the entire document, in particular, col. 1, line 15 to col. 2, line 18; col. 4, line 39 to col. 5, line 8; col. 6, lines 1-51; Examples) teaches a layered polymer scaffold including two or more assembled polymer membranes, wherein the scaffold has a thickness of about one (1) millimeter and each membrane has a surface with varying topology including at least one organized feature with at least one dimension of about 25 to 250 microns. Weiss et al teaches that the scaffold is made of a

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polymer material, but does not explicitly teach a synthetic polymer (or biopolymer) of a hydrogel. Kale et al (see the entire document, in particular, paragraphs [0112] - [0116], [0118] and [0125] - [0132]) teaches a scaffold made of a synthetic polymer (or biopolymer) of a hydrogel, and it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a synthetic polymer (or biopolymer) of a hydrogel as a scaffold material in the scaffold of Weiss et al in view of Kale et al in order to provide a scaffold for use in the repair or replacement of tissue.

7. Claims 31, 53, 60, 63 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al (U.S. Patent 6,143,293 A) in combination with Kale et al (U.S. Patent Application Publication 2002/0127711 A1).

Weiss et al (see the entire document, in particular, col. 1, line 15 to col. 2, line 18; col. 4, line 39 to col. 5, line 8; col. 6, lines 1-51; Examples) teaches a polymer scaffold including at least one membrane, wherein the scaffold has a thickness of about one (1) millimeter and each membrane has a surface with varying topology including at least one organized feature with at least one dimension of about 25 to 250 microns. Weiss et al teaches that the scaffold is made of a polymer material, but does not explicitly teach a synthetic polymer (or biopolymer). Kale et al (see the entire document, in particular, paragraphs [0112] - [0116], [0118] and [0125] - [0132]) teaches a scaffold made of a synthetic polymer (or biopolymer), and it

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would have been obvious to one of ordinary skill in the art at the time the invention was made to use a synthetic polymer (or biopolymer) as a scaffold material in the scaffold of Weiss et al in view of Kale et al in order to provide a scaffold for use in the repair or replacement of tissue.

8. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al (U.S. Patent 6,143,293 A) in combination with Kale et al (U.S. Patent Application Publication 2002/0127711 A1) as applied to claims 31, 53, 60, 63 and 66 above, and further in view of Masini et al (U.S. Patent Application Publication 2001/0043918 A1).

Weiss et al teaches a polymer scaffold including two or more assembled polymer membranes, but does not explicitly teach that the polymer membrane is a mesh. Masini et al (see the entire document, in particular, paragraphs [0027] - [0029] and [0086]) teaches a polymer scaffold including a membrane which may be a mesh, and such would have been obvious to one of ordinary skill in the art at the time the invention was made in Weiss et al in view of Masini et al in order to provide a scaffold for use in the repair or replacement of tissue.

Response to Arguments

9. Applicant's arguments with respect to claims 30, 31, 34, 38, 45, 46, 48, 49, 53, 60, 61 and 63-66 have been considered but are moot in view of the new ground(s) of rejection.

10. Weiss et al teaches a scaffold including a membrane having a surface with varying topology including at least one feature

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having a dimension of about 10 to 100 microns (see col. 8, line 39 to col. 9, line 46 of Weiss et al).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leo B. Tentoni whose telephone number is (571) 272-1209. The examiner can normally be reached on Monday - Friday (6:30 A.M. - 3:00 P.M.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina A. Johnson can

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be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leo B. Tentoni/
Primary Examiner, Art Unit 1791